

510(k) Summary

1.9F Vascu-PICC®

Summary of Safety and Effectiveness

Prepared May 15, 2009

General Information

Submitter:

MEDCOMP®
1499 Delp Drive
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JUN 17 2009

Contact:

Susan Pileggi
Regulatory Specialist

Device Trade Name: 1.9F Vascu-PICC®

Common Name: Peripherally Inserted Central Catheter (PICC)

Classification Name: LJS - Catheter, Intravascular, Therapeutic, Long-Term
Greater than 30 Days

CFR Reference: 21 CFR 880.5970, Class II

Classification Panel: General Hospital

Predicate Device:

Device Trade Name: 1.9F Vascu-PICC™

Common Name: Peripherally Inserted Central Catheter (PICC)

Classification Name: LJS -Catheter, Intravascular, Therapeutic, Long-
Term Greater than 30 Days

CFR Reference: 21 CFR 880.5970, Class II

Classification Panel: General Hospital

Premarket Notification: K061986, concurrence date August 15, 2006

Performance Standards: Performance standards have not been established by FDA under section 514 of the Federal Food, Drug, and Cosmetic Act.

Indications for Use: The 1.9F Vascu-PICC® is a long term catheter intended for central venous access via peripheral insertion in neonates, infants, and children. It may be used for administration of fluids, medication, and nutritional therapy.

Device Description:

- Designed for peripheral vein catheterization
- Comprised of a polyurethane material
- The lumen is connected to the extensions by a hub with a suture wing for placement.
- A clamp is provided on the extension tube to prevent air/fluid communication.
- A female luer connector provides the connection for intravenous administration.

Safety and Performance Tests

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the 1.9F Vascu-PICC® were previously cleared for similar applications by Medcomp, Inc.

Performance testing of the 1.9F Vascu-PICC® was conducted in accordance with the following international standards:

- *ISO 10555-1: 1997, Sterile Single Use-Intravascular Catheters, General Requirements*
- *ISO 10555-3: 1997, Sterile Single Use-Intravascular Catheters, Central Venous Catheters*
- *ISO 594-2: Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings*

Subject product testing has yielded acceptable safety and performance outcomes.

The results of these tests, in conjunction with the substantial equivalence claims effectively demonstrate that the 1.9F Vascu-PICC® is substantially equivalent to the cited predicate device.

Summary of Substantial Equivalence

Based on the indications for use and safety and performance testing, the 1.9F Vascu-PICC® meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 17 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan Pileggi
Regulatory Specialist
MedCOMP
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K091466
Trade/Device Name: 1.9F Vasu-PICC®
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: May 15, 2009
Received: May 18, 2009

Dear Ms. Pileggi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to [http://www.fda.gov/AboutFDA/Centers Offices/CDRH/CDRHOffices/ucm115809.htm](http://www.fda.gov/AboutFDA/Centers%20Offices/CDRH/CDRHOffices/ucm115809.htm) for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., M.A.

Acting Division Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: 1.9F Vascu-PICC®

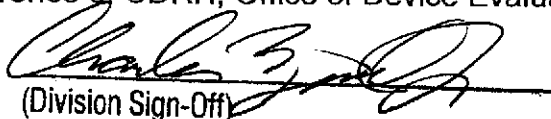
Indications for Use:

The 1.9F Vascu-PICC® is a long term catheter intended for central venous access via peripheral insertion in neonates, infants, and children. It may be used for administration of fluids, medication, and nutritional therapy.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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